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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,303	03/29/2007	Masayori Inouye	601-I-131PCTUS	9634
23565	7590	04/30/2010		
KLAUBER & JACKSON 411 HACKENSACK AVENUE HACKENSACK, NJ 07601			EXAMINER HIBBERT, CATHERINE S	
			ART UNIT	PAPER NUMBER
			1636	
			MAIL DATE	DELIVERY MODE
			04/30/2010	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/560,303

**Applicant(s)**

INOUE ET AL.

**Examiner**

CATHERINE HIBBERT

**Art Unit**

1636

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 14 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 7-10, 12 and 24-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-4, 7-10, 12, 26, 28 and 33-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24, 25, 27 and 29-32 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 December 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 4 February 2010
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This is the First Office Action on the Merits of US 10/560,303, filed 12 December 2005, which is a national stage entry of PCT/US04/18571, filed 14 June 2004, which claims benefit of US Provisional Applications 60/478,515 filed 6/13/2003 and 60/543,693 filed 2/11/2004.

Claims 5-6, 11, 13-23 are cancelled. Claims 1-4, 7-10, 12 and 24-35 are pending. Claims 1-4, 7-10, 12, 26, 28 and 33-35 are withdrawn herein. Claims 24, 25, 27, 29-32 are under examination in this action.

### ***Election/Restrictions***

Applicant's election without traverse of the invention of group II (claims 24-32) and of the species "ACA" as the type of recognition sequence and "MazF comprising SEQ ID NO:2 as the type of mRNA interferase, in the reply filed on 8/10/2009 is acknowledged.

Claims 1-4, 7-10, 12, 26, 28 and 33-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/10/2009.

### ***Information Disclosure Statement***

The IDS submitted 4 February 2010 has been considered by the examiner.

### ***Drawings***

The applicant's statement that the Figure 9 is in compliance with the Sequence Compliance rules has been fully considered but is not found persuasive. As such, the response filed by the applicant on 1/14/2010 is considered to be non-responsive. In addition, the CRF for Sequence Listing has been found to be defective as noted in the Notice mailed 1/29/2010.

However, in the interest of compact prosecution, it has been determined that these deficiencies do not preclude an examination on the merits. However, it is noted that a complete response to this action requires remedial action regarding the Sequence Compliance regarding Figure 9 and the defective CRF for reasons provided in the previous office mailings of 12/8/2009 and 1/29/2010 and presented herein.

The drawings are objected to because Figure 9 is not in compliance with the Sequence Compliance rules (see above). Corrected drawing sheets in compliance with 37 CFR 1.121(d) may be required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24, 25, 27, 29-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims are drawn to a method for making a polypeptide, the method comprising:(a) providing a nucleic acid sequence encoding said polypeptide, wherein the nucleic acid sequence encoding said polypeptide is mutated to replace mRNA interferase recognition sequences with an alternate triplet codon, wherein amino acid sequences of said polypeptide encoded by said mutated nucleic acid sequence are not altered by said mutating;(b) providing a nucleic acid sequence encoding an mRNA interferase, wherein said mRNA interferase recognizes said mRNA interferase recognition sequences; and (c) expressing the nucleic acid sequences of step (a) and (b), wherein expressing the nucleic acid sequences of step (a) and (b) produces the polypeptide in said cell. Thus, the applicant claims methods that require “a nucleic acid sequence encoding an mRNA interferase, wherein said mRNA interferase recognizes said mRNA interferase recognition sequences” as a materially essential element to the claimed method. It is noted that the instant specification discloses that the term mRNA interferase is intended to encompass unknown homologs and orthologs of the two identified mRNA interferases, MazF and PemK (e.g. paragraph 0009) and specifically to include unknown functional fragments of SEQ ID NO:2, as is particularly disclosed in dependent claims 25 and 32 which limit the term ‘the mRNA interferase’ of the base claims to being “MazF comprising

SEQ ID NO: 2 or a functional fragment thereof". Thus, the claims encompass methods using unknown functional sequences relating to homologs and orthologs of mRNA interferases and particularly unknown functional fragments of SEQ ID NO:2. Thus, the claims read on methods that require a broad genus of sequences that can perform the function of recognizing the mRNA interferase recognition sequences.

The written description requirement for a genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show applicants were in possession of the claimed invention. In the instant case, the specification does not sufficiently describe a representative number of functional fragments of SEQ ID NO:2 by actual reduction to practice or by disclosure of relevant identifying characteristics.

Applicant claims a functional fragments of SEQ ID NO:2 by function only, without any disclosed or known correlation between the elements and their function. The specification only provides teachings of SEQ ID NO:2. The specification does not teach how to mutate SEQ ID NO:2 and still have it function. The skilled artisan cannot envision a sufficient number of embodiments of the instant invention from the instant specification because the specification only discloses functional SEQ ID NO:2.

The state of the art at the time of filing does not provide sufficient information on the subject to overcome the deficiencies of the instant specification. There is no description in the

art that allows one to envision a representative number of functional fragments of SEQ ID NO:2 by disclosing structural or functional features of SEQ ID NO:2 so that one of skill in the art could envision the claimed invention. Thus the skilled artisan cannot consult the art at the time of filing to envision a sufficient number of embodiments of the instant invention to see that the applicant was in possession of the claimed genus.

Neither the specification of the instant application or the state of the art at the time of filing teaches a structure-function relationship for a representative number of functional functional sequence fragments. As a result, the skilled artisan would not be able to envision the claimed invention. Therefore applicant has not satisfied the written description requirement to show the skilled artisan that they were in possession of the claimed genus.

### ***Conclusion***

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE HIBBERT whose telephone number is (571)270-3053. The examiner can normally be reached on M-F 8AM-5PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/  
Primary Examiner, Art Unit 1636

Catherine Hibbert  
Examiner AU1636